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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|-------------|----------------------|-----------------------|------------------|
| 09/872,349 | 05/31/2001 | Sidney Pestka | PBLI-P01-007 | 1152 |
| 28120 | 7590 | 09/13/2005 | EXAMINER | |
| FISH & NEAVE IP GROUP ROPES & GRAY LLP ONE INTERNATIONAL PLACE BOSTON, MA 02110-2624 | | | HUFF, SHEELA JITENDRA | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 1643 | |

DATE MAILED: 09/13/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/872,349

Applicant(s)

PESTKA, SIDNEY

Examiner

Sheela J. Huff

Art Unit

1643

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 July 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 33 and 35-42 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 33 and 35-42 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 6/20/02, 1/25/02, 7/13/05

- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Response to Amendment

The amendment filed on 7/29/05 has been considered. Applicant's arguments are deemed to be persuasive-in-part.

Claims 33 and 35-42 are pending.

Both rejections under 35 U.S.C. 112, second paragraph, are withdrawn in view of applicant's amendments.

Response to Arguments
Claim Rejections - 35 USC § 112

Claims 33 and 35-42 remain rejected under 35 U.S.C. 112, first paragraph. The reasons for this rejection are of record.

Applicant provides a declaration by Dr. Walter in response to this rejection.

The declaration states that the current invention is not relying on crystallizing a protein, but of performing homology modeling of a protein based on crystal structure and that such a technique has been used many times in the art to model monoclonal antibodies (cites Exhibit B). The declaration further states that Table 1 shows that examination of other residues in the monoclonal backbone. Based upon this information, the monoclonal antibody is constructed, synthesized, transfected, expressed and purified. First, none of the references in Exhibit B were provided, so the Examiner cannot comment on the use of homology modeling. Second, table 1 does show the determination of Ser 224 and other residues and their potential to form H bond

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with surrounding residues. It is not clear if applicant is trying to make a correlation between the potential to form H bonds with the ability to be phosphorylated.

New Grounds of Rejection

Claims 35 and 36 and 42 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

a. In claims 35 and 36, the terminology "animal serum" does not further limit claim 33. Claim 33 is directed to human, mouse or fetal serum. "Animal" broadens the limitation in claim 33.

b. In claim 42, the fragment is limited to Fab. As stated in claim 33 the antibody or fragment is engineered to include at least one heterologous kinase site in the hinge region. Since Fab's do not contain a hinge region, claim 42 does not further limit claim 33. (see Illustrated Dictionary of Immunology ed., Cruse, 1997, p. 106 for picture of Fab).

Claims 33 and 35-42 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. **THIS IS A NEW MATTER REJECTION.**

Applicant has added the terminology "reduce". This terminology is not found in the specification. Therefore, it is new matter..

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sheela J. Huff whose telephone number is 571-272-0834. The examiner can normally be reached on Tuesdays and Thursdays from 5:30am to 2:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms can be reached on 571-272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Sheela J Huff
Primary Examiner
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